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STATE OF DELAWARE
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PUBLIC MEETING NOTICE:	CONTROLLED SUBSTANCE COMMITTEE
DATE AND TIME:	Wednesday, August 24, 2016 at 9:00 a.m.
PLACE:	Buena Vista Conference Center, Buck Library, First Floor, 661 S. DuPont Highway, New Castle, Delaware 19720
APPROVED:	October 26, 2017

MEMBERS PRESENT

Michael Kremer, DMD, Dental Representative, President
Philip Kim, M.D., Medical Representative
Art Jankowski, VMD, Veterinary Representative
Herb E. Von Goerres, R.Ph., Pharmacy Representative
Stephen Ruggles, PA-C, PA Representative
Mark Hanna, Public Representative

MEMBERS ABSENT

Luis Garcia, Jr., DPM, Podiatric Representative, Vice President
Jo Ann M. Baker, DNP, RN, FNP-C, Nursing Representative
Alex Zarow, R.Ph., Pharmacy Representative

DIVISION STAFF/DEPUTY ATTORNEY GENERAL

David W. Dryden, R.Ph., J.D., Director, Office of Controlled Substances
David Mangler, Director, Division of Professional Regulation
Christine Mast, Administrative Specialist III
Eileen Kelly, Deputy Attorney General
Stacey Stewart, Deputy Attorney General
Michelle McCreary, Pharmacist Compliance Officer

ALSO PRESENT

Hooshang Shanehsaz
Tejal Patel
Cheryl Heiks
Joel L Copper

CALL TO ORDER

Dr. Kremer called the meeting to order at 9:00 am.

REVIEW AND APPROVAL OF MINUTES

A motion was made by Mr. Von Goerres, seconded by Dr. Kim, to approve the minutes for June 22, 2016. The motion unanimously carried.

UNFINISHED BUSINESS

Review of Hearing Officer Recommendations - Bruce Grossinger, D.O., Steven D. Grossinger, D.O., John Brajer, M.D.

Ms. Stacey Stewart, Deputy Attorney General, Department of Justice rested on the recommendations. Ms. Eileen Kelly, Deputy Attorney General, Department of State reviewed the Hearing Officer Recommendations for the committee. Dr. Kremer requested Ms. Kelly to provide a summary of the recommendations. Ms. Kelly summarized each of the recommendations. The committee went into deliberation. A motion was made by Mr. Von Goerres seconded by Dr. Kremer to table the hearing officer recommendations until the Board of Medical Licensure and Discipline makes their decision on this matter. Dr. Kim abstained and the motion carried.

PRESIDENT's REPORT

No Report

NEW BUSINESS

DIRECTOR'S REPORT

Case/Diversion Review

Mr. Dryden stated that the Division of Professional Regulation received a Subpoena of PMP records from Family Court and requested his attendance during the hearing. Mr. Dryden appeared at the court as requested. His testimony was not required.

Mr. Dryden report that 2 robberies and 1 fire had been reported and inspections ensued. The fire was a total loss of the pharmacy. Mr. Dryden was on seen to ensure the proper transfer of drugs to another site occurred. There was a reverse distributor on seen and removed all drugs accordance to statute.

Mr. Dryden will be attending the NASCSA conference held in October.

Current Events

DEA Reports Increase in Heroin and Synthetic Fentanyl Use, Related Deaths

Problems resulting from the use and abuse of opioid drugs continue to rise, indicates Drug Enforcement Administration (DEA) in the 2016 *National Heroin Threat Assessment Summary*. Data newly added to the report this year show that deaths due to synthetic opioids, such as fentanyl and its analogues, increased 79% from 2013 to 2014. DEA notes that many people who are prescribed controlled substances for a legitimate medical purpose become addicted to opioid medications. "The reasons an individual shifts from one opiate to another vary, but today's heroin is higher in purity, less expensive, and can be easier to obtain" than controlled prescription drugs, indicates DEA. Although the heroin user population is substantially smaller than the population reporting current use of prescription pain relievers, marijuana, or cocaine, the heroin user population is increasing in size at a much faster rate than users of any other drug. In fact, the number of people reporting current heroin use almost tripled between 2007 (161,000) and 2014 (435,000), according to the Substance Abuse and Mental Health Services Administration's annual National Survey on Drug Use and Health.

US IP Rights Coordinator Advocates .Pharmacy Domain as Means of Protecting Consumers

During a recent United States Senate Committee hearing, Bruce Foucart, assistant director of the US National Intellectual Property Rights Coordination Center, advocated the NABP .pharmacy Top-Level Domain (TLD) as a means of protecting consumer well-being. The hearing, "Challenges and Opportunities for US Business in the Digital Age," took place on June 15, 2016, and addressed, in part, the problem of counterfeit goods, including pharmaceuticals, being sold over the internet, often endangering consumer safety. Foucart commended new domains such as .pharmacy, .med, .bank, and .insurance that verify the legitimacy of their domain name registrants prior to activating their websites. "Seals and logos can be faked online, but the .pharmacy domain is secure. Only safe, legal pharmacies are eligible for the .pharmacy domain. It's like baking the seal of legitimacy into the domain name itself," Foucart said. "We in law enforcement know we can't arrest or seize our way out of this problem, so we welcome efforts by industry like this to help us protect their customers and the economy." The Delaware Board of Pharmacy domain name set up has been recently completed. The site is www.deboard.pharmacy, which is registered and active for 5 years

OECD Report Cites .Pharmacy Domain as a Step Forward in the Fight Against Counterfeit Drugs

“The challenge of regulating online pharmacies is immense,” according to an April 2016 report by the Organization for Economic Co-operation and Development (OECD). The report, *Illicit Trade: Converging Criminal Networks*, describes the illegal trafficking of counterfeit medicines, noting that the problem is perpetuated through online drug sellers. The report cites NABP’s 2015 finding that 97% of websites selling prescription drugs online were operating outside the law, dispensing medicine without a valid prescription, and selling unapproved drugs. Under the heading “Great successes,” the report describes NABP’s .pharmacy domain launched in 2014 to establish “a safe place within cyberspace for consumers to purchase and get facts about medications.”

PMP Review

No Report

Inspection Report

No Report

Review of Proposed Legislative/Regulatory Changes

Mr. Mangler stated that Secretary Bullock would continue to review the regulations changes and would likely approve them in the next 60-90 days. He has up to 12 months to sign them. Mr. Mangler reported that Division of Public Health’s PDAC committee and the Medical Society is currently working to create educational materials and sample forms to support regulations requirements. Ms. Mast will provide the committee with a copy of the proposed regulations.

Dr. Kim spoke regarding the ability to flag and alert practitioners that there may be an issue with the prescribing practice as a whole or for an individual patient. Mr. Mangler reported that there will be a new release of the PMP program in October which will overhaul the entire site. He has requested information on the reporting upgrade details and how they may assist the practitioner as well as the PMP administrator.

Dr. Kim also cautioned practitioners regarding the following when utilizing the PMP and Urine testing:

- Uploaded PMP information can have a lag time of 1-2 days.
- Urine Tests can show a false positive or false negative result. Practitioners should be knowledgeable of test results and possible variables.
- Practitioners should encourage pharmacists to reach out for guidance for any concerns they may have after reviewing the PMP data to help prevent diversion.

Walgreens Safe Medication Disposal Kiosks

Mr. Dryden stated that Walgreens is requesting approval of Safe Medication Disposal Kiosks to be installed in the pharmacy next to the pharmacy department. Statute states they must be granted approval from the Office of Controlled Substances as well as the DEA to utilize these Kiosks. Mr. Dryden would like to inspect the facility and the proposed location of the Kiosk. He would also like to have it bolted to the floor.

Mr. Dryden also stated that the Dover Police Department contacted him regarding practitioners and researchers were disposing of their medications through the police department drop boxes. These registrants must use reverse distributors to return their controlled substances so that proper documentation is on file. These drop boxes are for patient prescribed unwanted medication disposal.

COMMITTEE REPORTS

Medical Examiner’s Report

No report.

DEA Report

No report

Substance Abuse Report

No Report

Law Enforcement Report

No Report

Regulatory Committee Report

No Report

Legislative Committee Report

No Report

COMMITTEE CORRESPONDENCE

None

OTHER BUSINESS BEFORE THE BOARD

None

PUBLIC COMMENTS

None

NEXT SCHEDULED MEETING

The next regular meeting will be held on October 26, 2016 at 9:00 am at the Buena Vista Conference Center, Buck Library.

ADJOURNMENT

A motion was made by Dr. Kremer, seconded by Mr. Von Goerres, to adjourn the meeting at 10:08 am. The motion carried.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Mast", written in a cursive style.

Christine Mast
Administrative Specialist III
Office of Controlled Substances